K040025

MAR - 2 2004

510(k) Summary of Safety and Effectiveness

510(k) Submitter: Streck Laboratories
7002 South 109th Street
La Vista, NE 68128

Official Correspondent: Carol Thompson, Quality Assurance Manager
(402) 537-5313

Date Prepared: January 7, 2004

Names of Device:
Trade Name: **A1c-Chex**
Common Name: Clinical Chemistry Test Systems
Classification Name: Quality Control Material, 21CFR862.1660

Predicate Device: MAS® Medical Analysis Diabetes Control – 510(k) #K023307

Description:
A1c-Chex is bi-level, whole blood based, assayed control for monitoring performance of analysis procedures for HbA1c. A1c-Chex should be treated the same as a patient specimen and tested following the instructions included with the instrument, kit or reagent being used. A1c-Chex intact RBC formulation allows users to verify all steps of analysis procedures, including lysing of the RBC.

Intended Use:
Monitoring the concentration of glycated hemoglobin is an important part of diabetes management. Hemoglobin A1c is the analyte measured by several methods, which are based on immunoassay, ion exchange and boronate affinity. A1c-Chex is designed as a whole blood material that closely mimics patient specimens and is able to monitor the complete analytical process.

Comparison with Predicate Device:
A1c-Chex and MAS® Diabetes Control are similar and have the same intended application.

A1c-Chex is a whole blood control. It should be treated the same as a patient specimen and tested following the instructions included with the instrument, kit or reagent being used. MAS® Diabetes Control is a lyophilized product prepared from human whole blood adjusted to specific concentrations of glycated hemoglobin.

A1c-Chex has an open vial stability of 30 days and MAS® Diabetes Control has an open vial stability of 14 days.

Testing Performed:
Studies were conducted to establish performance of A1c-Chex:
a.) Stability closed and open vial stability
b.) Percision Test
c.) Proposed Assay Sheet

Conclusions Drawn from the Tests:
Study results show A1c-Chex to be consistently reproducible, substantially equivalent to the predicate product, and stable for the entire product dating. A1c-Chex is a safe and effective product, which fulfills its intended use when used as instructed in the product package insert.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR - 2 2004

Ms. Kerrie Oetter
Quality Assurance/Regulatory Affairs
Streck Laboratories®, Inc.
7002 South 109th Street
LaVista, NE 68128

Re: k040025
Trade/Device Name: A1c-Chex
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJX
Dated: January 7, 2004
Received: January 7, 2004

Dear Ms. Oetter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K040025

Device Name: A1c-Chex

Indications For Use:

A1c-Chex is a bi-level whole blood based, assayed control for monitoring performance of analysis procedures for HbA1c.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use_____

(Optional Format 1-2-96)

Carol C Benson
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K040025